

A Randomized Controlled Comparison of Family-Based Treatment and Supportive Psychotherapy for Adolescent Bulimia Nervosa

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Context: Evidenced-based treatment trials for adolescents with bulimia nervosa are largely absent.

Objective: To evaluate the relative efficacy of family-based treatment (FBT) and supportive psychotherapy (SPT) for adolescents with bulimia nervosa.

Design: Randomized controlled trial.

Setting: The University of Chicago from April 1, 2001, through June 30, 2006.

Participants: Eighty patients, aged 12 to 19 years, with a *DSM-IV* diagnosis of bulimia nervosa or a strict definition of partial bulimia nervosa.

Interventions: Twenty outpatient visits over 6 months of FBT or SPT. Participants were followed up at 6 months posttreatment.

Main Outcome Measures: Abstinence from binge-and-purge episodes as measured by the Eating Disorder Examination. Secondary outcome measures were Eat-

ing Disorder Examination binge-and-purge frequency and Eating Disorder Examination subscale scores.

Results: Forty-one patients were assigned to FBT and 39 to SPT. Categorical outcomes at posttreatment demonstrated that significantly more patients receiving FBT (16 [39%]) were binge-and-purge abstinent compared with those receiving SPT (7 [18%]) ($P = .049$). Somewhat fewer patients were abstinent at the 6-month follow-up; however, the difference was statistically in favor of FBT vs SPT (12 patients [29%] vs 4 patients [10%]; $P = .05$). Secondary outcome assessment, based on random regression analysis, revealed main effects in favor of FBT on all measures of eating pathological features ($P = .003$ to $P = .03$ for all).

Conclusions: Family-based treatment showed a clinical and statistical advantage over SPT at posttreatment and at 6-month follow-up. Reduction in core bulimic symptoms was also more immediate for patients receiving FBT vs SPT.

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BULIMIA NERVOSA (BN) IS A disabling eating disorder with a prevalence of 1% to 2% among adolescents, while another 2% to 3% of adolescents present with bulimic symptoms that are clinically significant but do not meet full threshold criteria.¹⁻⁴ Physical health is often maintained despite binge eating and purging. However, medical morbidity is not uncommon and can include complications such as electrolyte disturbances, parotid gland swelling, and loss of dental enamel.^{5,6} Comorbid psychiatric disorders are relatively common and include mood and anxiety disorders and substance abuse disorders.^{7,8}

Significant progress has been made in developing and testing a range of efficacious treatments for adults with BN.⁹⁻¹⁴

However, systematic research in the treatment of this disorder among adolescents is largely absent. Only case series data for this patient population have been published, using family therapy,¹⁵ family-based treatment (FBT),¹⁶ or cognitive-behavioral therapy (CBT) with family involvement.¹⁷ Results from these reports are promising; for example, family therapy for 8 adolescents with BN showed significant changes in bulimic symptoms from the start of treatment to 1-year follow-up.¹⁵ In addition to these reports, the first controlled trial, to our knowledge, for adolescents with BN has recently been completed. Comparing family therapy with cognitive-behavioral-guided self-care, Schmidt and colleagues¹⁸ found no statistical differences at 6-month follow-up between treat-

DESIGN

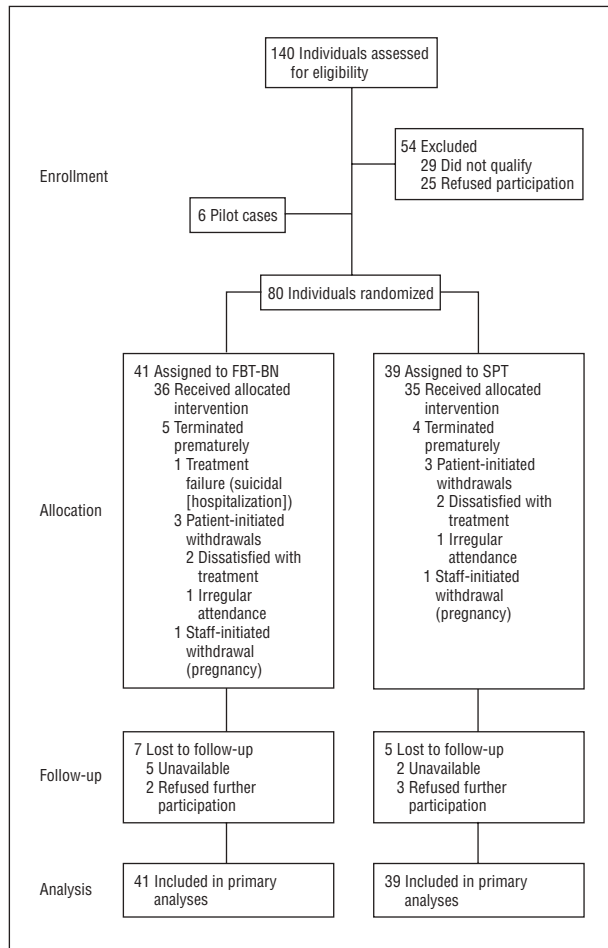


Figure 1. Study flowchart. FBT-BN, family-based treatment for bulimia nervosa; SPT, supportive psychotherapy.

ments on binge-and-purge abstinence rates (approximately 40% for both).

Only a limited number of treatment studies have been conducted for adolescents with BN, and most of these involve the patient's parents in the treatment. Family-based treatment was also shown to be helpful in a subgroup of adolescents with anorexia nervosa (AN) (ie, patients with onset of illness before the age of 19 years and duration of illness of < 3 years).^{19,20} Whereas AN and BN are distinct syndromes, considerable overlap in symptoms is common, and AN binge-and-purge subtype (about 20% of the samples studied) is typically responsive to FBT in terms of weight gain and reductions in binge-and-purge episodes. This suggests that parents are able to effectively decrease bulimic behaviors in addition to severe dieting.^{21,22} Family-based treatment is a promising therapy for adolescent AN and might, therefore, also be beneficial for adolescent BN.

The purpose of this study was to conduct a randomized controlled trial of 2 psychosocial treatments for adolescents with BN: FBT-BN, a task-oriented and focused treatment; and supportive psychotherapy (SPT), a non-specific control individual treatment. We hypothesized that FBT-BN, being a more focused and directive therapy than SPT, would have greater effect on the behavioral and attitudinal symptoms of BN.

The study compared FBT-BN with SPT for adolescents with *DSM-IV* BN or partial BN (those meeting all *DSM-IV* criteria except binge or purge frequency at once per week for 6 months). Family-based treatment for BN focuses on mobilizing parents to help their adolescents overcome their eating disorder, and SPT is nondirective and explores potential underlying issues of the eating disorder behavior. Supportive psychotherapy was chosen to control for nonspecific psychotherapeutic factors.

Eighty participants were randomly assigned to either FBT-BN or SPT. Randomization was performed by an independent biostatistician and was stratified in blocks of 4 or 6 for each therapist and each participant (ie, at initial assessment, qualifying participants were divided into 2 groups, full BN and partial BN, and then assigned to a therapist). After this assignment, participants were randomized to 1 of the 2 treatment conditions. This strategy was followed to ensure approximately equal representation of full and partial BN cases in both treatment conditions over time. Participants, study staff, and therapists were, therefore, unable to predict treatment assignment of the next subject in the stream. Consequently, 41 participants were randomized to FBT-BN and 39 to SPT.

Eight therapists (5 doctoral-level psychologists and 3 child psychiatry fellows), employed in our clinical program, administered the therapies during the study and were assigned cases from both treatment conditions in approximately equal numbers. Therapists were assigned pilot cases and trained by one of us (D.L.G.) before they were assigned randomized cases. Therapists were supervised weekly by one of us (D.L.G.) using an adherence measure for both treatments.

PATIENTS

Participants were recruited from April 1, 2001, through June 30, 2005, by advertising to clinicians, organizations, and clinics treating eating disorders. A total of 188 individuals were first screened by telephone to determine eligibility, and 140 were invited for assessment (**Figure 1**). At this assessment, the study was described in detail to the adolescent and her or his parents, who signed consent (assent in the case of participants aged < 18 years) before assessments were conducted. Of these participants, 111 met the criteria for the study. There were 6 pilot cases; 25 declined randomization, mostly because of disinterest in 1 or both treatments; and the remaining 80 were randomized to 1 of the 2 treatment modalities. Twenty-nine participants did not qualify. The institutional review board at The University of Chicago approved this study.

Participants, male or female, were eligible if they were aged 12 to 19 years, which represented the potential full range for precollege adolescents still living with their families or adult caregivers, and met the operational definition of the *DSM-IV* criteria for BN. Participants meeting the criteria for the "purging subtype" and the "nonpurging subtype" were included. In addition, participants who did not meet the *DSM-IV* binge-and-purge frequency criteria were included, provided they binged or purged at least once per week for 6 months and met all other *DSM-IV* criteria for BN (ie, the combined frequency of bulimic behaviors had to equal at least 24 episodes over the past 6 months, averaging about 1 episode per week). Our rationale for extending the period to 6 months was to include only those individuals with relatively established eating disorder behavior. Ethnicity was reported by the parents of participants and was assessed because (1) BN is more heterogeneous in terms of ethnicity than AN and (2) ethnic diversity in ado-

lescents with BN has not been explored in a treatment-seeking sample. Participants and their parents were eligible if they were willing to participate in the study and available for the duration of the study.

Participants were excluded if 1 of the following factors was present: associated physical or psychiatric disorder necessitating hospitalization; insufficient knowledge of English that would prohibit understanding treatment; current physical dependence on drugs or alcohol; current low body weight (body mass index [calculated as weight in kilograms divided by height in meters squared] ≤ 17.5), thereby excluding patients with an existing AN binge-and-purge subtype; current treatment for the eating disorder or current use of medication known to affect eating or weight; and physical conditions (eg, diabetes mellitus or pregnancy) or treatments known to influence eating or weight. Patients taking antidepressant medications were not excluded provided they were taking a stable dose for 4 weeks. However, given the established antibulimic effects of fluoxetine,¹³ patients taking 50 mg or more were excluded.

TREATMENTS

Treatments were conducted on an outpatient basis and consisted of 20 sessions over 6 months.

FBT for Adolescent BN

Family-based treatment for BN was developed as an adaptation of FBT for AN.²³ The manual was first pilot tested with a few cases and was subsequently adjusted for implementation in the study.²⁴ Although modified from that used with adolescent AN, this treatment shares many characteristics with the original Maudsley family treatment model. Family-based treatment for BN is impartial as to the cause of the eating disorder and assumes that the usual progress through adolescence is negatively affected by the disorder. Family-based treatment for BN proceeds through 3 phases, and treatment sessions are weekly in phase 1 (2-3 months), every second week in phase 2, and monthly in phase 3. In the first phase, treatment aims at empowering parents to disrupt binge eating, purging, restrictive dieting, and any other pathological weight control behaviors. It also aims to externalize and separate the disordered behaviors from the affected adolescent to promote parental action and decrease adolescent resistance to their assistance. Once abstinence from disordered eating and related behaviors is approached, the second phase of treatment begins, during which parents transition control over eating issues back to the adolescent. The third phase is focused on the ways the family can help to address the effects of BN on adolescent developmental processes.

SPT for Adolescent BN

Supportive psychotherapy for adolescent BN was an adaptation of the version of this treatment for adults with BN formulated by Walsh et al,¹³ which, in turn, was derived from the earlier work of Fairburn et al²⁵ for adults with BN. Manualized SPT was modified for use with adolescents with BN through on-site pilot testing and designed to provide a credible comparison treatment intended to represent the type of therapy that outpatients might typically receive from psychotherapists providing short-term treatment.¹³ Supportive psychotherapy contains no putative active therapeutic ingredients, such as stimulus-control or problem-solving techniques, or instruction or implicit advice on changes in diet and eating patterns. Thereby, SPT is designed not to overlap with CBT, interpersonal therapy, or analytic therapy. Supportive psychotherapy is nondirective and consists of 3 phases, with weekly sessions in phase 1 (2-3 months), every second week in phase 2, and monthly in phase 3. The

aim of the first phase is to establish a sound therapeutic relationship, obtain a detailed personal and family history and description of the eating problem and its development, and help the patient identify underlying problems that might be responsible for the eating disorder. The second phase has several aims: to encourage patients to explore underlying emotional problems, to facilitate self-disclosure and expression of feelings, and to foster independence and raise the issue of termination of treatment. The patient is encouraged to take the lead in this phase of treatment and use the sessions to talk about subjects that are of current concern. The third phase aims to review the underlying issues, and the patient is encouraged to consider the degree to which these issues remain a problem and what could be done in the future.

ASSESSMENT AND PROCEDURES

The areas of assessment included eating disorder symptoms and general psychiatric disorders. There were 4 major assessment points: pretreatment, midtreatment, posttreatment, and 6-month follow-up. An independent assessor not involved in the treatment delivery, but not blinded, conducted all assessments.

Specific Eating Disorder Pathological Features

The Eating Disorder Examination (EDE) is a standardized investigator-based interview that measures the severity of eating disorder psychopathological features and generates operational eating disorder diagnoses.²⁶ It is a measure of present state and, with the exception of the diagnostic items, is concerned with the preceding 4 weeks. It assesses the frequency of key behaviors (eg, overeating and purging) and the severity of eating disorder cognitions along certain dimensions (dietary restraint and concern about eating, shape, and weight). In comparisons of patients with AN, patients with BN, extreme dieters, and women in the general population, the EDE has demonstrated acceptable reliability (interrater agreement, 0.83), discriminant and concurrent validity, and sensitivity to change in the subject's eating disorder symptoms.²⁷ The EDE has been used in several treatment studies^{10,11} for adults and has shown to be valuable in the assessment of adolescents with eating disorders.²⁸ The EDE was used in the present study as the primary outcome measure and was administered at pretreatment, posttreatment, and 6-month follow-up.

To prevent subject burden, the questionnaire format of the EDE (EDE-Q) was used at midtreatment.²⁹

General Psychiatric Disorders and Psychological Functioning

The Schedule for Affective Disorders and Schizophrenia for School-Age Children is a semistructured diagnostic interview designed to ascertain past and current episodes of psychiatric disorders in children and adolescents.³⁰ The Schedule for Affective Disorders and Schizophrenia for School-Age Children has good concurrent and predictive validity and high interrater reliability.³¹ This measure was used to evaluate the presence of other psychiatric disorders at pretreatment only.

The Beck Depression Inventory is a 21-question scale with each answer rated from 0 to 3.³² This scale has been used in numerous studies of adolescent depression, particularly in psychotherapy trials.

The Rosenberg Self-esteem Scale is a widely used self-report instrument of 10 items measuring an individual's overall self-esteem.³³ The Rosenberg Self-esteem Scale and the Beck Depression Inventory were used at pretreatment, posttreatment, and 6-month follow-up.

Treatment Suitability and Expectancy and Therapeutic Alliance

Patients' perceptions of the suitability of the treatment being provided and patients' expectation of their treatment response were rated on visual analog scales at the start of treatment (sessions 1 and 2), midtreatment (session 10), and posttreatment (session 20).

The Helping Relationship Questionnaire measures 2 main aspects of the therapeutic relationship: the experience of being understood and supported and the experience of being involved in a collaborative effort with the therapist.³⁴ This 11-item self-report questionnaire was used to measure the quality of the therapist-patient relationship at midtreatment and posttreatment.

STATISTICAL ANALYSES

Statistical analysis for this study was performed by 1 of us (R.D.C.). Sample size calculation for this study was based on 3 controlled trials.^{13,19,21} It was calculated that for 80% power and a 2-tailed significance level of .05, it would be possible to detect an average difference between FBT-BN and SPT of 3 binge eating and purging episodes or a difference in remission rates of 25% between FBT-BN and SPT with a sample size between 31 and 36 participants per group. Assuming a dropout rate of 10% to 20%, the enrolled sample size was set at 40 participants per group.

Treatment groups were compared on sociodemographic and clinical characteristics at baseline using the Fisher exact test for dichotomous variables (eg, sex and family status), the χ^2 test for categorical variables (eg, ethnicity and comorbid diagnoses), and independent sample *t* tests for continuous measures (eg, age and body mass index).

The primary outcome category was the proportion of participants remitted, defined as no objective binge eating (OBE), subjective binge eating (SBE), or compensatory behavior in the previous 4 weeks, as determined by the EDE. Remission was determined separately at posttreatment and follow-up. The primary outcome analysis was based on intent-to-treat analysis. In those cases in which there were missing posttreatment or follow-up data, the pretreatment observation was carried forward to characterize that participant's response.¹¹ Groups were compared on remission at posttreatment and follow-up using a 2-tailed Fisher exact test with α set to .05. The secondary outcome category was the proportion of participants partially remitted, defined as no longer meeting the adjusted *DSM-IV* diagnostic criteria for the study. Family-based treatment for BN and SPT were compared at posttreatment and follow-up using the Fisher exact test.

A secondary analysis was performed using a mixed-effects linear regression model³⁵ to compare FBT-BN with SPT for participants on eating pathological features, depression, and self-esteem at midtreatment (3 months), posttreatment, and 6-month follow-up, controlling for pretreatment levels. Outcome measures included eating-disordered behavior frequencies (OBE, SBE, vomiting, and all compensatory behaviors) and subscales (restraint, eating concern, weight concern, shape concern, and global) from the EDE (EDE-Q at midtreatment) and total scores from the Rosenberg Self-esteem Scale and the Beck Depression Inventory. Analyses were performed on log-transformed variables for behavioral frequencies to satisfy the assumptions for the linear model. However, untransformed means and SDs are presented. Random regression models allow for the inclusion of individuals with missing data; consequently, no data imputation was performed. Comparisons between groups were based on the main effect for group, with a 2-tailed α of .05. Post hoc comparisons between groups at spe-

cific time points were based on a 2-tailed Bonferroni-corrected α of .02 (0.05/3).

RESULTS

PARTICIPANT CHARACTERISTICS

The mean age of the participants was 16.1 years, and their mean body mass index was 22.1. Most were female, with a mean duration of illness of 21.2 months. Thirty-seven participants (46%) presented with full BN, and 43 (54%) presented with partial BN. About half (38 [48%]) of the participants presented with a current mood disorder diagnosis. The prevalence of a current anxiety or substance use disorder was much lower (6 participants [8%]), while personality disorders are not diagnosable in young adolescents, who were most of this sample. Just less than one-third of participants were taking antidepressant medication (**Table 1**).

RANDOMIZATION AND ATTRITION

There were no differences between FBT-BN and SPT on any sociodemographic, diagnostic, or other clinical variable at pretreatment (Table 1). Treatment attendance was in excess of 85% of expected sessions, and there were no differences between the 2 treatment modalities in terms of the average number of sessions attended (FBT-BN: mean, 17.6 [SD, 5.0]; SPT: mean, 18.1 [SD, 4.2]; $t_{78} = -0.52$, $P = .60$). There were no differences between FBT-BN and SPT in terms of patients' perception of the suitability of the treatment or patients' perception of their treatment response at the outset of treatment, midtreatment, or posttreatment ($P = .24$ to $P = .65$). Similarly, there were no differences between the 2 treatment modalities in terms of the quality of the therapist-patient relationship as perceived by the patient at midtreatment (FBT-BN: mean, 20.2 [SD, 11.7]; SPT: mean, 19.6 [SD, 9.3]; $t_{67} = 0.24$, $P = .81$) or at posttreatment (FBT-BN: mean, 22.9 [SD, 8.5]; SPT: mean, 26.0 [SD, 6.1]; $t_{60} = -1.68$, $P = .10$).

Six participants initiated withdrawal from treatment during the study, either because of dissatisfaction with treatment ($n = 4$) or because of irregular attendance ($n = 2$), 2 were withdrawn because of pregnancy (1 after 2 treatment sessions and 1 after 11 sessions), and 1 was hospitalized for suicidality. Of these 9 participants, 5 were allocated to FBT-BN and 4 to SPT (Fisher exact test, $P > .99$). Twelve participants were not available or refused the 6-month follow-up assessment, 7 allocated to FBT-BN and 5 to SPT (Fisher exact test, $P = .76$). Another 5 participated in the follow-up assessment, but chose to complete the EDE by telephone interview. Seventy-one participants (89%) were available for the posttreatment assessment, and 68 (85%) were available for the 6-month follow-up assessment.

TREATMENT OUTCOME

There were no significant pretreatment differences between treatment groups for the EDE, depression, or self-esteem (**Table 2**).

Table 1. Baseline Participant Characteristics by Treatment Group^a

Characteristic	FBT-BN Group (n = 41)	SPT Group (n = 39)	Total (N = 80)	Statistics
Age, y ^b	16.0 (1.7)	16.1 (1.6)	16.1 (1.6)	$t_{78} = -0.43, P = .67$
Female sex	40 (98)	38 (97)	78 (98)	Fisher exact test, $P > .99$
BMI ^b	21.8 (2.5)	22.4 (3.4)	22.1 (3.0)	$t_{78} = -0.99, P = .33$
No. diagnosed as having BN/partial BN	18/23	19/20	37/43	Fisher exact test, $P = .82$
Duration of illness, mo ^b	22.3 (20.4)	20.1 (24.4)	21.2 (22.3)	$t_{76} = 0.43, P = .67$
Antidepressant medication use	16 (39)	10 (26)	26 (32)	Fisher exact test, $P = .24$
Ethnicity ^c				
White	31 (76)	20 (51)	51 (64)	$\chi^2_3 = 7.44, P = .06$
Hispanic	6 (15)	10 (26)	16 (20)	
African American	4 (10)	5 (13)	9 (11)	
Other	0	4 (10)	4 (5)	
Family status				
Intact	27 (66)	19 (49)	46 (58)	Fisher exact test, $P = .18$
Not intact	14 (34)	20 (51)	34 (42)	
K-SADS primary diagnosis ^c				
No diagnosis	13 (32)	17 (44)	30 (38)	$\chi^2_4 = 2.24, P = .69$
Current depression	21 (51)	17 (44)	38 (48)	
Current anxiety	2 (5)	1 (3)	3 (4)	
Other diagnosis	1 (2)	2 (5)	3 (4)	
Subthreshold diagnosis	4 (10)	2 (5)	6 (8)	

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); FBT-BN, family-based treatment for bulimia nervosa; K-SADS, Schedule for Affective Disorders and Schizophrenia for School-Age Children; SPT, supportive psychotherapy.

^aData are given as number (percentage) of each group unless otherwise indicated.

^bData are given as mean (SD).

^cPercentages may not total 100 because of rounding.

Table 2. Eating Disorder Pathological Features, Depression, and Self-esteem at Pretreatment, Midtreatment, Posttreatment, and 6-Month Follow-up by Treatment Group^a

Variable	Pretreatment ^b		Midtreatment ^c		Posttreatment		6-mo Follow-up	
	FBT-BN (n = 41)	SPT (n = 39)	FBT-BN (n = 35)	SPT (n = 33)	FBT-BN (n = 36)	SPT (n = 35)	FBT-BN (n = 34)	SPT (n = 34)
EDE								
OBE ^d	18.4 (28.1)	18.9 (22.3)	4.5 (16.5) ^e	8.8 (12.7)	4.1 (14.8)	3.2 (5.1)	2.5 (6.8)	5.4 (13.7)
SBE ^d	9.9 (16.6)	7.6 (10.1)	3.7 (7.0) ^e	11.1 (18.8)	4.5 (13.3)	4.6 (8.6)	2.8 (6.9)	2.4 (5.2)
Vomiting ^f	34.5 (31.0)	33.2 (33.5)	6.1 (9.0) ^e	21.4 (26.6)	4.8 (9.4) ^e	17.4 (26.0)	10.1 (21.8)	14.5 (27.7)
All compensatory behaviors ^f	49.5 (36.9)	50.2 (42.3)	8.9 (10.8) ^e	27.9 (30.2)	6.9 (10.2) ^e	22.3 (28.6)	12.4 (21.6)	17.9 (28.0)
Restraint ^f	3.8 (1.3)	3.7 (1.7)	1.9 (1.6) ^e	3.2 (1.9)	1.3 (1.5) ^e	2.1 (1.6)	1.3 (1.5)	1.9 (1.6)
Weight concern ^f	3.7 (1.4)	4.1 (1.3)	2.1 (1.7) ^e	3.6 (1.8)	1.8 (1.6)	2.6 (1.7)	1.6 (1.5)	2.3 (1.5)
Shape concern ^f	4.0 (1.4)	4.2 (1.1)	2.6 (1.6) ^e	3.9 (1.7)	1.8 (1.6)	2.7 (1.7)	1.7 (1.5)	2.7 (1.9)
Eating concern ^f	2.9 (1.4)	2.9 (1.2)	1.5 (1.5) ^e	3.0 (1.5)	1.0 (1.5)	1.5 (1.4)	0.8 (1.2)	1.3 (1.5)
Global ^f	3.6 (1.1)	3.7 (1.1)	2.0 (1.5) ^e	3.4 (1.5)	1.5 (1.4)	2.2 (1.4)	1.4 (1.2)	1.9 (1.4)
RSE	27.6 (6.8)	27.2 (5.1)	NA	NA	22.0 (7.7)	23.2 (6.4)	21.4 (7.3)	22.6 (7.2)
BDI	25.8 (12.2)	24.6 (11.8)	NA	NA	12.4 (12.6)	13.7 (12.9)	12.6 (12.1)	11.6 (10.3)

Abbreviations: BDI, Beck Depression Inventory; EDE, Eating Disorder Examination; FBT-BN, family-based treatment for bulimia nervosa; NA, data not available; OBE, objective binge eating; RSE, Rosenberg Self-esteem Scale; SBE, subjective binge eating; SPT, supportive psychotherapy.

^aData are given as mean (SD).

^bThere were no significant differences between the 2 groups ($P = .29$ to $P = .90$).

^cMeasured from the EDE questionnaire.

^d $P < .05$, main effect for group.

^eGreater improvements were seen in the FBT-BN vs the SPT group ($P < .02$).

^f $P < .01$, main effect for group.

Remission rates (ie, no OBE, SBE, or compensatory behavior for the previous 4 weeks) were significantly higher for FBT-BN at posttreatment (FBT-BN, 16 participants [39%]; SPT, 7 participants [18%]; Fisher exact test, $P = .049$) and at 6-month follow-up (FBT-BN, 12 participants [29%]; SPT, 4 participants [10%]; Fisher exact

test, $P = .05$) (**Figure 2A**). Partial remission rates (ie, the percentage of participants no longer meeting entry criteria for the study) at posttreatment were higher for the FBT-BN group (17 participants [41%]) vs the SPT group (8 participants [21%]), although this difference only approached significance (Fisher exact test, $P = .06$). At follow-

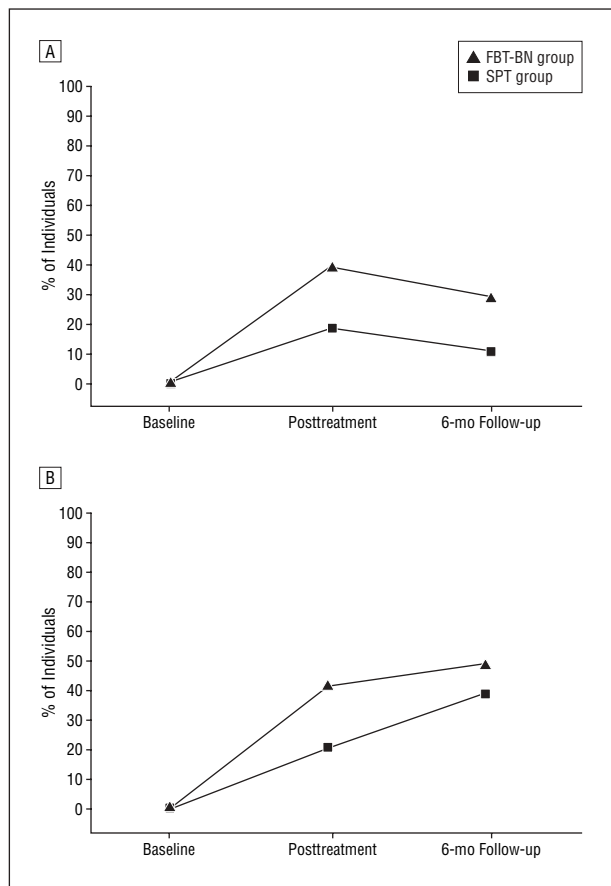


Figure 2. Remission (A) and partial remission (B) by treatment group (41 individuals in the FBT-BN group and 39 in the SPT group). In A, $P = .049$ at posttreatment and $P = .05$ at 6-month follow-up; and in B, $P = .06$ at posttreatment and $P = .38$ at 6-month follow-up. Abbreviations are explained in the legend to Figure 1.

up, the percentage of participants no longer meeting entry criteria for the study was 49% ($n = 20$) for the FBT-BN group compared with 38% ($n = 15$) for the SPT group (Fisher exact test, $P = .38$) (Figure 2B). There was no difference in remission rates between BN and partial BN at posttreatment (Fisher exact test, $P = .22$) or follow-up (Fisher exact test, $P = .26$).

Secondary outcome assessment, based on a mixed-effects linear regression model, revealed main effects in favor of FBT-BN on all measures of eating pathological features (Table 2) (OBE: $F_{1,77} = 5.77$, $P = .02$; SBE: $F_{1,77} = 5.09$, $P = .03$; vomiting: $F_{1,77} = 11.10$, $P = .001$; all compensatory behaviors: $F_{1,77} = 8.37$; $P = .005$; restraint: $F_{1,77} = 8.72$, $P = .004$; weight concern: $F_{1,77} = 7.01$, $P < .01$; shape concern: $F_{1,77} = 8.93$, $P = .004$; eating concern: $F_{1,77} = 9.23$, $P = .003$; global EDE: $F_{1,77} = 9.07$, $P = .004$), but no differences between groups in self-esteem ($F_{1,77} = 0.96$, $P = .33$) and depression ($F_{1,77} = 0.13$, $P = .72$). Post hoc comparisons (Table 2) revealed greater midtreatment reductions for FBT-BN on all behavioral (ie, OBE, SBE, vomiting, and all compensatory behaviors) and attitudinal (restraint, weight concern, shape concern, eating concern, and global) measures on the EDE-Q, with effect sizes ranging from 0.29 (OBE) to 0.89 (eating concern). At posttreatment, significantly greater reductions for FBT-BN were found for vomiting (effect size, 0.62), all compen-

satory behaviors (effect size, 0.68), and EDE restraint (effect size, 0.50). No significant differences were obtained between groups at the 6-month follow-up, although mean levels for FBT-BN were lower on all EDE measures except SBE.

Pretreatment antidepressant use was not significantly related to remission status at posttreatment (Fisher exact test, $P = .44$) or follow-up (Fisher exact test, $P = .14$). Antidepressants were used by 26 of 80 participants (32%) at pretreatment, 28 of 72 (39%) at midtreatment, 30 of 71 (42%) at posttreatment, and 19 of 61 (31%) at follow-up. This did not differ between the FBT-BN and SPT groups and was not associated with remission status at posttreatment or follow-up (Fisher exact test, $P = .06$ to $P = .24$). Participation in psychotherapy during follow-up was similar for the FBT-BN group (9 of 30 or 30%) and the SPT group (9 of 31 or 29%) (Fisher exact test, $P > .99$).

COMMENT

The present study was designed to test the efficacy of FBT-BN, a therapy adapted from its version for AN, relative to SPT, a nonspecific supportive treatment adapted from its version for adults with BN. Supportive psychotherapy was chosen to control for nonspecific therapeutic variables and because it might represent treatment that many adolescents with eating disorders receive in the community.¹³ Our hypothesis was that FBT-BN would bring about greater improvement in behavioral and attitudinal symptoms of BN. In terms of our categorical outcomes, results of this study indicate a clinical and a statistical advantage for FBT-BN over SPT at posttreatment and at 6-month follow-up. Intent-to-treat analyses demonstrated that 16 (39%) of those treated with FBT-BN were fully remitted at posttreatment, which was significantly better than those treated with SPT (7 participants [18%]). Follow-up analyses revealed that FBT-BN maintained this advantage over SPT, albeit by a narrower margin (12 participants [29%] vs 4 participants [10%]). Similarly, 17 (41%) of those treated with FBT-BN were partially remitted at posttreatment compared with 8 (21%) treated with SPT. This difference approached significance. At follow-up, 20 (49%) patients receiving FBT-BN and 15 (38%) of those receiving SPT no longer met the adjusted *DSM-IV* diagnostic criteria for BN. This difference was not significant.

Our secondary analyses also demonstrated clinical and statistical advantages for FBT-BN over SPT on the behavioral and attitudinal components of the EDE and the EDE-Q. In particular, reduction in core bulimic symptoms was more immediate for patients receiving FBT-BN vs those receiving SPT. This was demonstrated in that FBT-BN showed significant advantage over SPT on all core bulimic symptoms by midtreatment, making FBT-BN seem more efficient in terms of early symptomatic relief. This finding is of interest given the adult literature on early treatment response.³⁶ However, a detailed time course analysis of response in the FBT group is beyond the scope of the present study. At posttreatment, those treated with FBT-BN demonstrated larger reductions in vomiting and all compensatory behaviors and in the re-

straint subscale on the EDE. At 6-month follow-up, it would seem as if SPT has “caught up” with FBT-BN because our results revealed no significant differences between the 2 treatment groups, echoing findings for CBT vs interpersonal psychotherapy for adult BN.¹¹ There were no differences between FBT-BN and SPT at posttreatment or follow-up in terms of general psychopathological features (ie, depression and self-esteem).

Abstinence rates in the FBT-BN group were modest at posttreatment and diminished by follow-up. While these results may in part be because we adhered to a high threshold for remission in this study, relatively low abstinence rates are nevertheless a concern and highlight the challenge in achieving successful treatment for most patients with BN, adults or adolescents. Nevertheless, these rates are at least comparable to those typically achieved in controlled trials of CBT for adult BN¹¹ and those reported for family therapy and individual CBT-guided self-help in the only other controlled trial¹⁸ for adolescents with BN. While Schmidt et al¹⁸ show that neither treatment in their study has a clear benefit over the other, the present study more convincingly demonstrates the benefits of FBT-BN vs SPT. One reason for this finding might be that our study was sufficiently powered to demonstrate the potential benefits of an active treatment over a nonspecific control treatment. Schmidt and colleagues acknowledge that the sample size was a limitation of their study, which may have been underpowered to detect differences on some of the outcomes between 2 active treatments.

Several strengths of the present study give us confidence in our findings. First, this study was sufficiently powered, with minimal participant dropout at posttreatment and at follow-up. Second, existing treatment manuals were used; FBT-BN was adapted from an adolescent AN manual and SPT from an adult BN manual. Both manuals were pilot tested before their use in the randomized part of this study, while the quality of each therapy was monitored by 1 of us (D.L.G.) weekly throughout the study. In addition, therapeutic alliance and treatment suitability and expectancy were high and at similar levels for both treatment modalities, demonstrating that patients perceived the control treatment as credible. Third, an independent assessor using the gold standard measure for eating disorder pathological features, the EDE, conducted all assessments.

As for limitations, this assessor was not blinded in terms of treatment assignment at the posttreatment and follow-up assessments. Consequently, the potential for bias cannot be ruled out. Second, therapy sessions were not audiorecorded for quality control. However, there was little concern for treatment overlap, and adherence was monitored by 1 of us (D.L.G.) in weekly supervision. Third, it would be difficult to rule out the possibility that patients in the FBT-BN group were motivated to underreport their symptoms in ongoing assessments more so than patients in the SPT group by virtue of parental involvement in the former. Fourth, while adolescent studies have shown that EDE scores obtained through self-report vs investigator report closely parallel each other,²⁸ a potential confound using EDE-Q at midtreatment cannot be ruled out. However, EDE-Q data were used only to establish differences between treatments and not to

establish changes over time. Fifth, a significant minority of patients presented with a comorbid mood disorder that warranted antidepressant medication treatment throughout the study. While it would be difficult to tease apart any potential benefit due to the antilimbic effects of the selective serotonin reuptake inhibitors, we did not find any differences in outcome between those patients who received medication and those who did not receive medication. However, a separate study examining moderators and mediators of treatment response will address these issues in more detail.

To our knowledge, this study is only the second randomized controlled trial for adolescent BN completed to date. Results suggest that FBT-BN is promising in the amelioration of symptomatic behavior for this disorder. Categorical outcomes and early treatment effects demonstrate the superiority of FBT-BN over SPT. However, we do not know whether it is family involvement or the focus on eating behavior that is key to good treatment outcome. Moreover, abstinence rates between 30% and 40% leave considerable room for improvement. One obvious way to address this shortcoming would be a comparison of FBT-BN and CBT. The work of Schmidt et al¹⁸ and recent case series work at Stanford University, Stanford, California, that adapted CBT to incorporate parents in treatment¹⁷ indicate that this is an important issue to address. Future work should also attempt to improve on the fact that many adolescents seeking treatment for an eating disorder were excluded from participation, despite the expanded inclusion criteria for this study.

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